Privileging Nightmares and the Legal Ramifications

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Objectives

- CMS Requirement
  - Who requires privileges
  - Specific criteria
  - “Opting out”

- Privileges
  - Organization
  - Criteria: Initial vs Reappointment
  - Current with latest technology
  - FPPE/OPPE

- Legal Ramifications
  - Health care reform focus on quality outcomes and impact on privileging
  - Non-compliance = increased legal liability and loss of revenue
  - Maximizing peer review privilege protections
The Joint Commission:
- "any individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. When standards reference the term 'licensed independent practitioner,' this language is not to be construed to limit the authority of a licensed independent practitioner to delegate tasks to other qualified health care personnel (for example, physician assistants [PAs] and advanced practice registered nurses [APRNs]) to the extent authorized by state law or a state's regulatory mechanism or federal guidelines and organizational policy."

The US Health Resources and Services Administration (HRSA) also uses the term when talking about credentialing providers for health clinics.
Why Do We Privilege?

▪ To protect patients
▪ To protect the reputation of the organization
▪ To protect the assets of the organization from negligent credentialing lawsuits
Healthcare organizations determine a scope of services that can be provided within the organization – and then determine the practitioners who are qualified and currently competent to direct, manage, coordinate and provide the scope of services.
Why Do We Privilege?

Remember him?!?
Why Do We Privilege?
Why Do We Privilege?

- **Blind Eye: The Terrifying Story Of A Doctor Who Got Away With Murder**, James B. Stewart, June 15, 2000


- **Kadlec v. Lakeview Anesthesia Associates**, 527 F.3d 412 (5th Cir, 2008)

Case Study
Christopher Duntsch

- MD & PhD – Univ. of Tenn. Health Science Center
- Neurosurgery residency – 2004-2010
  - Program Director
  - Sent to impaired MD program
  - Not allowed to operate independently
- Post residency stayed in research and ran Discgenics
- July 1, 2011 recruited to Baylor Plano
Residency letter
- “His work ethic, character, and ability to get along with others were beyond reproach.”

Fired from group after first surgery

November 2011 Kenneth Fennel – wrong site surgery

December 30, 2011 – Robert Passmore - Asst. surgeon grabs Duntsch and begs him to stop. Nurses fail to report incident
Christopher Duntsch

- **January 11, 2012** - Barry Morguloff – Dr. Randall Kirby was the assistant surgeon – Surgery was a “horror”
- **February 12, 2012** – Jerry Summers – Woke up a paraplegic
- **Summary suspension** – not reported – Privileges reinstated
- **March 12, 2012** – Kelly Martin – Dead – Post operative hemorrhage following laminectomy
- **April 2012** – Suspended & Resigned
Christopher Duntsch

- April 20, 2012 resignation letter states relocating practice
- April 20, 2012 reference letter provided to Duntsch from Baylor
April 20, 2012

Christopher Duntsch, MD
4705 Alliance Blvd.
Pavilion I — Suite 630
Plano, Texas 75093

Dear Dr. Duntsch:

On behalf of the Medical Executive Committee of the Medical Staff of Baylor Regional Medical Center at Plano, I am authorized to notify you of the following:

All investigations with respect to any areas of concern regarding Christopher D. Duntsch, M.D. have been closed.

As of this date, there have been no summary or administrative restrictions or suspensions of Dr. Duntsch’s Medical Staff membership or clinical privileges during the time he has practiced at Baylor Reg. Medical Center at Plano.

Yours Very Truly

[Signature]

Patricia Sproles, CPCS
Director, Medical Staff Services
Christopher Duntsch

- July 2012 – Dallas Medical Center grants temporary privileges
- July 2012 – Floella Brown dies from post-operative hemorrhage
- July 2013 – Texas Medical Board suspends license
- March 2014 – lawsuit filed against Baylor
- July 2015 - Indicted
Lessons Learned (Again)

- Credentialing & Privileging –
  - Watch for red flags & follow up

- Impairment –
  - Identify and manage

- Action –
  - Take when necessary

- Reporting –
  - Follow the law

- Reference letters
  - Factual – notice to others

- Information Sharing
  - Proactive
Why Do We Privilege?

▪ Reasons for development of delineated clinical privileges:
  ▪ Legal requirements have established corporate liability
  ▪ Regulatory requirements
    ▪ Centers for Medicare and Medicaid Services (CMS)
    ▪ The Joint Commission, DNV, HFAP
Who must be privileged?

- CMS Requirement
  - Medical Staff
    - MD, DO
    - Other practitioners appointed by the Governing Body
      - DMD, DDS, DPM, DC, APRN, PA, CRNA, CNM, PsyD, LCSW

“For hospitals that use Joint Commission accreditation for deemed status purposes: The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope of practice laws, the medical staff may also include other categories of physicians as listed at 482.12(c)(1) and non physician practitioners who are determined to be eligible for appointment by the governing body.” TJC MOS.01.01.01 EP13
The following is from a letter from the Center for Medicare and Medicaid Services (CMS) dated November 2004:

- The hospital’s Governing Body must ensure that all practitioners who provide a medical level of care and/or conduct surgical procedures in the hospital are individually evaluated by its Medical Staff and that those practitioners possess current qualifications and demonstrated competencies for the privileges granted.

- State Survey Agency (SA) surveyors are to determine whether the hospital’s privileging process and its implementation of that process comply with the hospital Conditions of Participation (CoPs).
The following is an excerpt from a letter from the Center for Medicare and Medicaid Services (CMS) dated November 2004:

“Specific privileges for each category must clearly and completely list the specific privileges or limitations for that category of practitioner. The specific privileges must reflect activities that the majority of practitioners in that category can do and that the hospital can support. It cannot be assumed that a practitioner can perform every task/activity/privilege listed/specified for the applicable category of practitioner. The individual practitioner’s ability to perform each task/activity/privilege must be assessed and not assumed.”

“If the practitioner is not competent to perform one or more tasks/activities/privileges, the list of privileges is modified for that practitioner. Hospitals must assure that practitioners are competent to perform all granted privileges.”
CMS Requirements Related to Privileges cont.

- “The Medical Staff must actually examine each individual practitioner’s qualifications and demonstrated competencies to perform each task/activity/privilege he/she has requested from the applicable scope of privileges for their category of practitioner. Components of practitioner qualifications and demonstrated competencies would include at least: current work practice, special training, quality of specific work, patient outcomes, education, maintenance of continuing education, adherence to medical staff rules, certifications, appropriate licensure, and currency of compliance with licensure requirements. All practitioners providing a medical level of care and/or conduct surgical procedures either directly or under supervision, whether employed by the hospital, physician or other entity, or contracted, must be individually evaluated. Board certification, certification, or licensure in and of itself is not recognized as an appropriate basis to bestow or award any or all of the privileges included in a particular practitioner’s category.”
Privileging is the process by which a health care organization, after reviewing an individual provider’s credentials and performance, authorizes the practitioner to perform a specific scope of patient care services within the organization. Privileging involves the following four distinct activities:

- **Step 1**: Determining which clinical procedures or treatments the organization will offer and support.
- **Step 2**: Determining what training, skills, behaviors, and experience are required for authorization to perform each clinical procedure or treatment.
- **Step 3**: Determining whether applicants for privileges meet these requirements and officially granting or denying the requested privileges.
- **Step 4**: Monitoring the individuals who are granted privileges to ensure their continued competence and practice within the scope of privileges granted.

*Source: Assessing Hospital Staff Competence, 2nd Edition (2007 - Joint Commission Resources)*
Current Focus of Clinical Privileging Systems

▪ What does “current competence” mean?
▪ Two dimensions of current competence are:
  ▪ Recent clinical activity
  ▪ Quality performance information
When was the last time you REALLY read your delineation of privileges (DOPs)?

- Are they current?
- Are they organized; easy to understand?
- Do they meet the CMS requirements?
- Laundry List vs Core Privileges?
- Do they have criteria/qualifications: Initial vs Reappointment?
- Is the criteria located on the DOP or in a separate document?
- Is there state licensing and/or scope of practice laws to perform procedures?
- Are board certification requirements included? Do they match the bylaws?
- Do specialty privileges contain manufacturer's recommendations for training?
- Is your FPPE included? Is it relevant?
Delineation of Privileges (DOPs)

- **Organization**
  - **Qualifications**
    - Education/Training
      - Residency/Fellowship
    - State Licensure
    - Board Certification
      - MOC
    - Continuing Education
    - Initial Competency
      - Requisite experience
    - Reappointment Criteria
      - Current competency, OPPE
    - Additional qualification
      - ACLS, PALS
Delineation of Privileges (DOPs)

- **Criteria**
  - Required education/training
    - Medical School
    - Residency/Fellowship
  - Board Certification
    - MOC
    - Additional qualifications
  - Current competence
    - Case logs
    - Program Director recommendation
- **Reappointment**
  - OPPE data
  - Peer references
  - Department Chair assessment
Delineation of Privileges (DOPs)

- Core/Primary Privileges
  - Procedures or privileges any well trained physician should be able to perform after completion of post-graduate training and your facility can support
  - Meet ACGME requirements
  - Separated into systems or sub-groups of privileges
  - Physician able to “opt out” of a privilege
  - Are they allowed to “write in” privileges?
Delineation of Privileges (DOPs)

- Core/Primary Privileges
  - Paragraph format
  - Laundry list but no criteria
  - Separate documents
  - Grouped by systems/types
  - Able to opt out of core privileges

- Extraneous Information
  - Lengthy documentation
    - Procedural (Moderate/Deep) Sedation policy
    - Allied Health Scope of Practice
    - Whole segments of medical staff bylaws
    - Manufacturer's instructions
Privileging Nightmares

- Sample Privileges:

  “Privileges include admission, evaluation and diagnoses of injuries, and disorders of the colon, rectum, anus, and perianal areas. Privileges also include procedures and consultations related to the colon, rectum, and anus; including but not limited to, endoscopic procedures of the colon; total colonoscopy and flexible sigmoidoscopy, both diagnostic and therapeutic; incisional and ventral herniorrhaphy; surgery of the large and small intestine rectum and anus; and management of surgical complications.”
### Surgery

#### Delineation of Clinical Privileges

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominoperineal resection</td>
<td>Laparoscopy, diagnostic, appendectomy, cholecystectomy, incidental gynecological procedures, biopsy, mobilization, and catheter positioning</td>
</tr>
<tr>
<td>Amputations, above the knee, below the knee; toe, transmetatarsal, digits</td>
<td>Laparotomy for diagnostic or exploratory purposes or for management of intra-abdominal surgery or trauma</td>
</tr>
<tr>
<td>Anoscopy</td>
<td>Liver biopsy (intra operative), liver resection</td>
</tr>
<tr>
<td>Appendectomy</td>
<td>Management of burns</td>
</tr>
<tr>
<td>Breast: Complete mastectomy with or without axillary lymph node dissection</td>
<td>Management of intra-abdominal trauma, including injury, observation, paracentesis, lavage</td>
</tr>
<tr>
<td>Breast: Complete mastectomy with or without axillary lymph node dissection</td>
<td>Management of multiple trauma</td>
</tr>
<tr>
<td>Breast: Complete mastectomy with or without axillary lymph node dissection</td>
<td>Management of soft-tissue tumors, inflammations, and infection</td>
</tr>
<tr>
<td>Breast: Complete mastectomy with or without axillary lymph node dissection</td>
<td>Operations on gallbladder, biliary tract, bile ducts, hepatic ducts, excluding biliary tract reconstruction</td>
</tr>
<tr>
<td>Cervicectomy</td>
<td>Pancreatectomy, total or partial</td>
</tr>
<tr>
<td>Circumcision</td>
<td>Pancreatic sphincteroplasty</td>
</tr>
<tr>
<td>Colectomy (abdominal)</td>
<td>Parathyroidectomy</td>
</tr>
<tr>
<td>Colon surgery for benign or malignant disease</td>
<td>Peritoneal venous shunts, shunt procedure for portal hypertension</td>
</tr>
<tr>
<td>Colectomy, colectomy</td>
<td>Peritoneovenous drainage procedures for relief or ascites</td>
</tr>
<tr>
<td>Correction of intestinal obstruction</td>
<td>Proctosigmoidoscopy, rigid with biopsy, with polypectomy; tumor excision</td>
</tr>
<tr>
<td>Drainage of intra-abdominal, deep pelvic, abscess</td>
<td>Pyelotomy</td>
</tr>
<tr>
<td>Emergency thoracotomy</td>
<td>Radical regional lymph node dissections</td>
</tr>
<tr>
<td>Enteric fistula, management</td>
<td>Removal of ganglion (palm or wrist; flexor sheath)</td>
</tr>
<tr>
<td>Endoscopy (infraoperative)</td>
<td>Repair of perforated viscus (gastric, small intestine, large intestine)</td>
</tr>
<tr>
<td>Enteroctomy (feeding or decompression)</td>
<td>Scalene node biopsy</td>
</tr>
<tr>
<td>Esophageal resection and reconstruction</td>
<td>Sclerotherapy</td>
</tr>
<tr>
<td>Distal esophagogastric suture</td>
<td>Selective vagotomy</td>
</tr>
<tr>
<td>Excision of fistula in anastomotic, rectal lesion</td>
<td>Sigmoidoscopy, fiberoptic with or without biopsy, with polypectomy</td>
</tr>
<tr>
<td>Excision of pilonidal cyst/muscularalization</td>
<td>Skin Grafts (partial thickness, simple)</td>
</tr>
<tr>
<td>Excision of thyroid tumors</td>
<td>Small bowel surgery for benign or malignant disease</td>
</tr>
<tr>
<td>Excision of thymic duct cyst</td>
<td>Splenectomy (trauma, staging, therapeutic)</td>
</tr>
<tr>
<td>Gastric operations for cancer (radical, partial, or total gastrectomy)</td>
<td>Surgery of the abdominal wall, including management of all forms of hernias, including diaphragmatic hernias, inguinal hernias, and orchidectomy in association with hernia repair</td>
</tr>
<tr>
<td>Gastroduodenal surgery</td>
<td>Thoracentesis</td>
</tr>
<tr>
<td>Gastrotomy</td>
<td>Thoracoabdominal exploration</td>
</tr>
<tr>
<td>Gastrotomy (feeding or decompression)</td>
<td>Thyroidectomy and neck dissection</td>
</tr>
<tr>
<td>Gastrectomy, feeding or decompression</td>
<td></td>
</tr>
</tbody>
</table>
Applicant must submit evidence of training and current competency to request

Additional Procedures include:

- Use of laser [initial request: completion of approved residency/fellowship that included training in laser
  principles OR completion of an approved 8-10 hr CME course that included training in laser principles AND
  at least 3 procedures in part 12 months or completion of training within past 12 months; renewal request: at
  least 10 procedures in past 2 years]

- Hip resurfacing [completion of residency that included hip resurfacing or completion of specialized
  training that included proctoring by an experienced surgeon; at least 25 performed in past 12 months]

**Orthopaedic Surgery of the Spine** (requires completion of an accredited fellowship in orthopaedic
surgery of the spine or experience deemed by the American College of Spine Surgery to be equivalent to a 12
month approved spine fellowship program or current certification by the American Board of Spine
Surgery)(initial request: at least 20 procedures in past 12 months or completion of training within past 12
months; renewal requests: at least 40 procedures in past 2 years)

- Endoscopic minimally invasive spinal surgery
- Laminectomy, laminotomy, fusion reconstruction of the spine and its contents, including instrumentation
- Lumbar puncture
- Management of traumatic, congenital, developmental, infectious, metabolic, degenerative, and rheumatologic
  disorders of the spine
- Scoliosis and kyphosis instrumentation
- Spinal cord surgery for decompression of spinal cord or spinal canal, rhizotomy, cordotomy, dorsal root entry
  zone lesions, tethered spinal cord, or other congenital anomalies
- Kyphoplasty/vertebroplasty [retrospective review of first 5 cases on initial requests, at least 5 cases in past 2
  years for renewal]

**Orthopaedic Surgery of the Hand** (requires completion of an accredited fellowship in hand surgery)(initial request: at least 30 procedures in past 12 months or completion of training within past 12
months; renewal requests: at least 100 procedures in past 2 years)

- Wound closure, including skin grafts, tissue flaps, and free microvascular tissue transfer
- Tenodesis, tendon transfer and balancing, tendon sheath release
- Nerve repair and reconstruction and nerve decompression and transportation
- Management of fractures and dislocations, with and without internal fixation, and injuries to joints and
  ligaments
- Bone grafts and corrective osteotomies
- Joint and tendon sheath repairs
- Management of arthritis
- Joint repair and reconstruction, thumb reconstruction
- Management of tumors of the bone and soft tissue
- Replantation and revascularization
- Impairment (related to hand/upper extremity)
- Fasciotomy, deep incision and drainage of infection, and wound debridement
- Management of congenital deformities
- Management of upper extremity vascular disorders and insufficiencies
- Articuloplasty
## Sample Medicine privileges:

<table>
<thead>
<tr>
<th>Diagnosis And Treatment Of Disorders And Diseases</th>
<th>Requested</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Of The Cardiovascular System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Respiratory System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Gastrointestinal System Including</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Of The Kidneys, Bladder And</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Male And Female Genitourinary</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Central And Peripheral Nervous</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Musculo-Skeletal System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Endocrine System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Metabolism</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Immune System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Joints</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Hematologic System</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of Neoplasia</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of The Skin</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Of Infectious Diseases</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Privileging Nightmares

Sample Surgical privileges:

|---------------------------|-------------------|----------------|----------------|------------------|----------------------|---------------|----------------|-------------------|----------------|--------------------------|-------------------|---------------|------------------|-----------------------|-----------------|-----------------|
Sample Medical Specialty privileges:

<table>
<thead>
<tr>
<th>MEDICAL SPECIALTY AREA(s)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please indicate below your medical specialty area(s) for which you will be requesting privileges.</td>
<td></td>
</tr>
</tbody>
</table>

- Allergy/Immunology
- Cardiology
- Critical Care Medicine
- Dermatology
- Endocrine/Metabolic
- Gastroenterology
- Hematology/Oncology
- Hospice Care
- Infectious Diseases
- Internal Medicine
- Nephrology
- Neurology
- Nuclear Medicine
- Pain Management
- Pathology (Anatomic)
- Pathology (Clinical)
- Psychiatry
- Pulmonary Medicine
- Radiation Oncology
- Radiology
- Other: ____________
Privileging Nightmares

- Focused Professional Practice Evaluation
  - Concurrent/Prospective/Retrospective review
  - Do you require too many procedures or just enough attest to competency? Is it overkill?
  - Specific to specialty: i.e. Pathology or Radiology
  - 360* evals included; eval from OR Supervisor

- Sample statements:
  - “Retrospective evaluation of a minimum of 5 cases of varied types of anesthesia (general, regional, sedation).”
  - “Retrospective evaluation to include pre-operative work-up, surgical plan and post-operative course of events of 5 major surgeries.”
  - Five retrospective case reviews chosen to represent a diversity of medical conditions and management challenges.
Privileging Nightmares

- **Specific Reappointment Criteria**
  - General overarching requirement
    - “Applicant must provide documentation of provision of clinical services (# cases) representative of the scope and complexity of privileges requested during the previous 24 months.”
  - Specific number of cases for each procedure(s) requested
    - Difficult for the physician to meet for procedures rarely performed
    - Hard to obtain data on AHPs
  - Manufacturer’s recommendation
    - Could include didactic, observation, simulation and/or supervised cases as a path to clinical competence
    - Expectation of the FDA organizations will adhere to recommended training/proctoring requirements
Privileging Nightmares

- Specific Reappointment Criteria cont.
  - OPPE Indicators
    - Specialty specific indicators
    - Case reviews by peers
    - Complaints/incident reports
  - CME Requirements
    - Meet state licensing requirements
  - Additional requirements
    - ACLS/BLS/PALS/NRP certification
    - Fluoroscopy
    - Requirements for core privileges: i.e. “Basic laparoscopic privileges required for Complex Laparoscopic/Minimally Invasive Procedures”
Privileging Nightmares

▪ Special/Advanced Privileges:
  ▪ Additional qualifications/Training certification
  ▪ Current with latest technology
  ▪ Manufacturer’s guidelines for training/competence
  ▪ Required number of performed cases/procedures
  ▪ Cases performed with a mentor
  ▪ Separate FPPE requirements
  ▪ Reappointment criteria
  ▪ CME requirements
Privileging Nightmares

- **Periodic Check Up:**
  - Review privileges for current content
    - Set up a table for scheduled reviews; even if no changes are made
  - Still current with latest technology
  - New procedures/techniques
  - Has facility added new services:
    - Robotic surgery
    - Bariatric Surgery
    - PET Scan
Privileging Nightmares

- **Negligent Credentialing**
  - Avoid negligent credentialing lawsuits
    - Must be in compliance with CMS/TJC and/or facility regulatory compliance
  - DOPs must be current
  - Match your Medical Staff bylaws/rules & regulations
  - Credentialing & privileging policies/procedures
  - Reflect what your physicians/practitioners are able to do within your facility
  - Assure physicians/practitioners are appropriately privileged to ensure patient safety
Negligent Credentialing

Darling v. Charleston Community Memorial Hospital (1965)
- Hospitals have an independent duty to patients
- Reasonable care in selection of physician and granting of privileges

Elam v. College Park Hospital (1992)
- Hospitals owe a duty to insure the competency of its medical staff
(7) Require that the medical staff establish controls that are designed to ensure the achievement and maintenance of high standards of professional ethical practices including provision that all members of the medical staff be required to demonstrate their ability to perform surgical and/or other procedures competently and to the satisfaction of an appropriate committee or committees of the staff, at the time of original application for appointment to the staff and at least every two years thereafter.
Legal Ramifications

- Health care reform focus on quality outcomes and impact on privileging

- How non-compliance with privileging requirements lead to increased legal liability and loss of revenue

- Maximizing peer review privilege protections
FCA Liability for Negligent Credentialing

▪ **Worthless Services**

▪ **USA v. Azmat**
  - “From the very first endovascular procedures he performed in Satilla’s cath lab, it was obvious to the cath lab nursing staff that Azmat was not qualified or competent to perform endovascular procedures.”
  - Satilla finally took action but agreed with Azmat not to report if he agreed not to perform the procedures until competent.
  - Satilla settled for $840,000.
Privileges must be

- **Individualized**
  - Practitioner
  - Facility/Service

- **Relevant**
  - Current
  - Realistic

- **Supported by Objective Evidence**
  - Training
  - Experience

- **Continuously Monitored**
  - OPPE
Privileging Nightmares & the Legal Ramifications
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Thank you!